UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,587	07/29/2003	Kei Roger Aoki	17328CON5	1664

7590 07/27/2005

EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1656	

Stephen Donovan
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,587	AOKI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 31-38 are pending.

Applicants' amendment filed on June 10, 2005 is acknowledged. Applicants' response has been fully considered. Claims 28-30 have been cancelled, claim 31 has been amended, and new claims 32-38 have been added. Thus, claims 31-38 are examined.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

2. The previous rejection of claims 28-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U. S. Patent 6,869,610, is withdrawn in view of applicant's cancellation of the claims in the amendment filed June 10, 2005.

3. The previous rejection of claims 28-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-32 of co-pending application 10/630,206, is withdrawn in view of applicant's cancellation of the claims in the amendment filed June 10, 2005.

4. The previous rejection of claims 28-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending application 11/003,677, is withdrawn in view of applicant's cancellation of the claims, applicants' submission of a terminal disclaimer, and applicants response at page 5 in the amendment filed June 10, 2005.

Withdrawn Claim Rejections - 35 USC § 112

5. The previous rejection of claims 28-31 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's cancellation of the claims, applicants' amendment to the claim, and applicants response at pages 6-7 in the amendment filed June 10, 2005.

Withdrawn Claim Rejections - 35 USC § 102

6. The previous rejection of claims 28-30 under 35 U.S.C. 102(b) as being anticipated by Binder (WO 95/30431), is withdrawn in view of applicant's cancellation of the claims, and applicants response at page 8 in the amendment filed June 10, 2005.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 31-34, 37 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by Borodic *et al.* (WO94/15629).

Borodic *et al.* teach a method of treating post operative myofascial pain using a botulinum toxin locally administered to the muscle associated with the pain and the pain is diminished in the past 4 years for the patient (see page 14, line 21-33 and page 17-18, Example 2; claims 31, 34, 37 and 38), where the botulinum toxin can be types A to G, or commercially available type A (page 8, lines 22-30; claims 32-33).

8. Claims 31-35, 37 and 38 are rejected under 35 U.S.C. 102(a) as anticipated by Barwood *et al.* (Developmental Medicine & Child Neurology 42, 116-121 (February 2000).

Barwood *et al.* teach using botulinum toxin A (BTX/A) to treat the postoperative pain in children with spastic cerebral palsy (CP), where the pain is often attributed to muscle spasm (abstract). Five to 10 days before the scheduled date of surgery, the child was injected with effective amount of BTX/A in saline at two sites close to the specific adductor muscles, and equal volumes of normal saline were used for placebo injections, it was found that the BTX/A group has a significant reduction in postoperative pain during their admission as compared to placebo group, and the effect lasts at least 3-6 months (pages 117-120; Table II; claims 31-35, 37 and 38).

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Previous rejection of claim 31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-5 of U. S. Patent 6,869,610 is maintained, and claims 32-38 have been added. Applicant's arguments have been fully considered, and the response to the argument is shown below.

Claims 31-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-5 of U. S. Patent 6,869,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 31-38 in the instant application disclose a method for treating post-operative incisional wound pain, the method comprising administering a botulinum toxin to an afflicted area of a patient. This is obvious variation in view of claims 4-5 of the patent which disclose a method for treating pain that occurs after a surgical procedure, comprising peripheral administration of a therapeutically effective amount of a botulinum toxin to a patient. Both sets of claims cite a method of treating post-operative pain, comprising peripheral administration of a botulinum toxin. Thus, claims 31-38 in present application and claims 4-5 in the patent are obvious variations of a method of treating post-operative pain, comprising peripheral administration of a botulinum toxin.

Response to Arguments

Applicants indicate a terminal disclaimer against U. S. patent 6,869,610 has been enclosed to obviate the rejection, however, the terminal disclaimer against 6,869,610 has not been filed. The rejection is maintained.

10. Previous rejection of claim 31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 7-12 of U. S. Patent 6,464,986 is maintained, and claims 32-38 have been added. Applicant's arguments have been fully considered, and the response to the argument is shown below.

Claims 31-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 7-12 of U. S. Patent 6,464,986.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 31-38 in the instant application disclose a method for treating post-operative incisional wound pain, the method comprising administering a botulinum toxin to an afflicted area of a patient. This is obvious variation in view of claims 1, 3, 5 and 7-12 of the patent which disclose a method for treating post-operative pain, comprising peripheral administration of a therapeutically effective amount of a botulinum toxin to a patient. Both sets of claims cite a method of treating post-operative pain, comprising peripheral administration of a botulinum toxin. Thus, claims 31-38 in present application and claims 1, 3, 5 and 7-12 in the patent are obvious variations of a method of treating post-operative pain, comprising peripheral administration of a botulinum toxin.

Response to Arguments

Applicants indicate a terminal disclaimer against U. S. patent 6,464,986 has been enclosed to obviate the rejection, however, the terminal disclaimer against 6,464,986 has not been filed. The rejection is maintained.

11. Previous rejection of claim 31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-32 of co-pending application 10/630,206 is maintained, and claims 32-38 have been added. Applicant's arguments have been fully considered, and the response to the argument is shown below.

Claims 31-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-32 of co-pending application 10/630,206. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 31-38 in the instant application disclose a

method for treating pain caused by neuralgia, or treating post-operative incisional wound pain, the method comprising administering a botulinum toxin to an afflicted area of a patient. This is obvious variation in view of claims 1, 4, 5, 9, 12, 13 and 28-32 of the co-pending application which disclose a method for treating pain, the method comprising administration such as peripheral administration of a botulinum toxin to a mammal. Both sets of claims cite a method of treating pain such as neuralgia or post-operative pain, comprising administration such as peripheral administration of a botulinum toxin. Thus, claims 31-38 in present application and claims 1, 4, 5, 9, 12, 13 and 28-32 in the co-pending application are obvious variations of a method of treating pain such as neuralgia or post-operative pain, comprising administration of a botulinum toxin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate a terminal disclaimer against U. S. application 10/630,206 has been enclosed to obviate the rejection, however, the terminal disclaimer against U. S. application 10/630,206 has not been filed. The rejection is maintained.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
July 26, 2005